

### REMARKS

Claims 41-42, 44-48, 50-54, 56-63, 65-68, 70-87 and 91-93 are pending, wherein claims 41, 59, 65, 72, 77, 81 and 86 have been amended. Reconsideration and allowance for the above-identified application are now respectfully requested.

The independent claims have been amended to specify that the claimed dental bleaching compositions include a carrier that is “free of an amount of an abrasive that would externally abrade a tooth surface such that the dental bleaching composition does not externally abrade a tooth surface when applied thereto” so as to be “substantially free of abrasives”, “non-abrasive” and/or capable of “non-abrasively bleaching and desensitizing a person’s teeth”. Support for this is found in the following quoted passages of the originally filed specification:

*The compositions are preferably substantially free of abrasives, as the compositions are typically not scrubbed onto the teeth. When using abrasive toothpastes, people typically brush for less than 60 seconds, which is not enough time to cause a noticeable whitening effect. On the other hand, scrubbing teeth with an abrasive material for an extended period of time can be harmful to the tooth enamel. Therefore, in order to allow for extended bleaching, whitening and opacification of teeth, the inventive compositions will preferably not include substantial quantities of an abrasive.*

Application, page 5, line 20 – page 6, line 2 (emphasis added).

As indicated hereinabove, the dental whitening compositions of the present invention preferably do not include an abrasive. *Abrasives only externally treat a tooth*; however, it is believed that whitening and opacification of a tooth is achieved by the action of the bleaching agent and potassium nitrate internally within a tooth. Not only are abrasives unnecessary but inclusion of abrasives in the composition may be undesirable in preferred embodiments where it is desired for the whitening composition to remain on the teeth for an extended period of time (i.e., greater than about 3 minutes).

Application, page 20, lines 1-7 (emphasis added).

*wherein the dental bleaching composition is substantially free of abrasives.*

Application, page 35, lines 13-14 (emphasis added).

The inventive dental bleaching compositions are to be contrasted with “conventional desensitizing toothpaste compositions” that include a substantial quantity of an abrasive in order to externally abrade a tooth surface and which are formulated and used in a manner so as to treat past sensitivity rather than sensitivity caused by a dental bleaching agent:

Moreover, the compositions of the present invention should be contrasted with conventional desensitizing tooth paste compositions formulated with large quantities of abrasives (e.g., 20% or more by weight) and high concentrations of potassium nitrate (e.g., up 10% by weight) which are intended to contact the teeth during daily brushing (typically for 60 seconds or less). *Such compositions are formulated to treat past, rather than prospective, tooth sensitivity. They do not treat sensitivity caused by simultaneous contact of the teeth with a dental bleaching agent, particularly since no significant bleaching and sensitization of a person's teeth are likely using peroxide-containing toothpastes due to the extremely short contact times.*

Application, page 9, lines 14-22 (emphasis added).

The claims as amended claim dental bleaching compositions and methods that are patentable over the cited art, which consists of the combination of McLaughlin (US 6,108,850) and Shimada et al. (US 5,626,837). As Shimada et al. was only cited for the limited purpose of allegedly suggesting the inclusion of antimicrobial agents in a dental bleaching and desensitizing composition, the patentability of the independent claims can be established by distinguishing the claimed invention from the toothpaste composition of McLaughlin, which is formulated so as to include an abrasive and be brushed onto a person's teeth in order to abrasively clean a person's teeth.

As discussed in the previous response, McLaughlin, when properly construed as required by *Graham v. John Deere* and the examination guidelines articulated in the MPEP, discloses an abrasive bleaching and desensitizing toothpaste that is suitable for scrubbing or brushing onto a person's teeth. *See* col. 3, lines 38-49; col. 4, lines 9-12; col. 7, lines 1-26). McLaughlin cannot, in the absence of improper hindsight, be reasonably construed as somehow disclosing a dental bleaching and desensitizing composition that includes 1) a dental bleaching agent, 2) potassium nitrate in the specified range(s), 3) a solvent, and 4) a tackifying agent but that is simultaneously substantially free of abrasives.

The only place where McLaughlin discloses a dental bleaching composition that also includes potassium nitrate in an amount that is allegedly within the claimed ranges is the toothpaste composition of Example 4. Col. 7, lines 1-26. This example notably fails to list a solvent and a tackifying agent as part of the toothpaste. Nevertheless, the Examiner interprets the term "paste carrier" as inherently (*i.e.* necessarily) including both a solvent *and* a tackifying agent while also excluding an abrasive. This is an unreasonable interpretation and mischaracterization of McLaughlin and contradicts the clear teachings of McLaughlin.

McLaughlin clearly teaches that both water (the alleged “solvent”) and thickener (the alleged “tackifying agent”) are optional components of the “vehicle” and are included whenever an “abrasive material” is also included in the vehicle:

**When an abrasive material is included the vehicle may contain water, humectant, surfactant, and a thickener.** Examples of humectants are glycerin, sorbitol, and polyethylene glycol (molecular weight 200-1000). Both mixtures of humectants and single humectants can be employed in the composition of the invention. **Thickeners may be incorporated in the abrasive component** such as natural and synthetic gums such as carrageenan, xanthan gum, sodium carboxymethyl cellulose, starch, polyvinylpyrrolidone, hydroxyethylpropylcellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose, and hydroxyethyl cellulose.

Col. 3, lines 50-61 (emphasis added).

In view of the foregoing, because the “paste carrier” of Example 4 of McLaughlin is interpreted by the Examiner as including both a “solvent” and a “tackifying agent” it necessarily follows that the “paste carrier” also includes an “abrasive material”. That is the only logical reading of the combined teachings at col. 3, lines 50-61 and col. 7, lines 1-26 of McLaughlin. To argue otherwise would require the use of impermissible hindsight reconstruction, using the present Application as a guide to selectively reinterpret the plain meaning of McLaughlin.

On the other hand, because the Examiner chooses to interpret Example 4 of McLaughlin as definitively **not** including an “abrasive material” because no abrasive material is mentioned (only 83.5% by weight of a “paste carrier” of unspecified ingredients), it necessarily follows that the “paste carrier” must likewise be devoid of a solvent and tackifying agent under this interpretation. That is the only logical reading of the combined teachings at col. 3, lines 50-61 and col. 7, lines 1-26 of McLaughlin, because the water and tackifying agent are described as being optional components that are only included “when an abrasive material is [also] included” within “the vehicle”. To argue otherwise would require the use of impermissible hindsight reconstruction, using the present Application as a guide to selectively reinterpret the plain meaning of McLaughlin.

In short, the Examiner cannot have it both ways. He cannot reasonably interpret the “paste carrier” of Example 4 of McLaughlin as simultaneously including both a “solvent” and “tackifying agent” while also being “substantially free of abrasives”. Such an argument contradicts the clear and unambiguous teachings of McLaughlin and can only be the result of

improper hindsight bias. In view of this, Applicants submit that the claims as now presented are patentable over the combination of McLaughlin and Shimada et al. because they neither teach nor suggest a dental bleaching and desensitizing composition that includes 1) a dental bleaching agent, 2) potassium nitrate in the specified range(s), 3) a solvent, and 4) a tackifying agent and which is also “substantially free of abrasives”.

The method claims are further patentable over the combination of McLaughlin and Shimada et al. because they further claim “contacting the person’s teeth with said non-abrasive dental bleaching composition without scrubbing or brushing for a time sufficient to bleach teeth and in a manner so as to not abrade the person’s teeth”. In contrast, McLaughlin teaches that the disclosed toothpaste compositions are applied to teeth using a toothbrush: “*the invention provides a device for whitening teeth, consisting of a toothbrush with a head and a handle*”. Col. 2, lines 1-3 (emphasis added); col. 2, lines 8-14 and Figures 1-3 (describing a “toothbrush” as the means of applying the toothpaste of McLaughlin); col. 5, lines 16-61; col. 6, lines 36-46; col. 7, lines 1-26 (explaining that the “whitening composition” of Example 4 is applied to teeth using a toothbrush). While other methods of applying a dental composition are described in McLaughlin, they are not described in connection with the abrasive toothpaste composition of Example 4. *See* col. 4, lines 26-27 (bleaching composition in the form of “mouthwash”); col. 4, line 54 – col. 5, line 15 (form of bleaching composition is unspecified); col. 6, lines 53-59 (composition “used to bathe the teeth”).

Moreover, as further argued in the previous amendment, it is well known to those of ordinary skill in the art that the term “toothpaste” refers to dentifrices that typically include a substantial quantity of an abrasive. For example, a publicly available web document attached to the previous amendment as Exhibit A teaches the following: “A modern *toothpaste* has many things to do. It *must have abrasives* to scour off bacterial films.... Hydrated silica is the transparent *abrasive* used in gel toothpastes, and in the clear parts of striped toothpaste.” Ingredients – Toothpaste, <http://sci-toys.com/ingredients/toothpaste.html> (01/26/2010), p. 1 (emphasis added).

As further evidence that the toothpaste composition in Example 4 of McLaughlin includes an abrasive, Applicants previously submitted the publicly available web document attached as Exhibit B to the previous amendment, which teaches the following: “*Toothpaste abrasives* scrub away plaque, help remove food stains from teeth, and polish tooth surfaces.” Dental Health, Toothpaste—is There A Difference?, HealthNews More Natural Health,

<http://www.healthnews.com/dental-health/toothpaste-the-difference-200.html> (01/26/2010), p. 2 (emphasis added).

Applicants also referred to the publicly available web document attached as Exhibit C to the previous amendment, which teaches the following: “**Abrasives:** Abrasives give toothpaste its cleaning power. They remove stains and plaque, as well as polish teeth. Common abrasives include calcium phosphates, alumina, calcium carbonate, and silica. *Toothpaste should be abrasive enough to remove plaque and stains, but not abrasive enough to damage tooth enamel.*” Everything You Wanted to Know About Toothpaste, Toothpaste – What’s In It?, <http://www.saveyoursmile.com/toothpaste/toothpaste-c.html> (01/26/2010), p. 1 (italics added).

Finally, statements made during the prosecution of McLaughlin by the examiner and the patentee confirm that the toothpaste compositions of McLaughlin objectively included an abrasive. In the office action dated April 8, 1999 (“Office Action”), a copy of which was attached to the previous amendment as Exhibit D, the Examiner rejected claims 1-6, 9, 11, 16-21 and 23 under 35 U.S.C. § 102(b) as being anticipated by Cornell (U.S. Patent No. 5,032,178). Office Action, p. 4. In making this rejection, the examiner stated that “[s]ince a *paste* is disclosed, an *abrasive* would be *inherent* in the formulation.” *Id.* (emphasis added). This is further evidence that one of ordinary skill in the art would reasonably consider the term “paste” to imply that the composition of Example 4 of McLaughlin is “abrasive”. For the PTO to now assert that the term “paste” does not inherently describe an abrasive composition would contradict its own previous position.

In response to the Office Action, the patentee filed an amendment dated July 12, 1999 (“Amendment”), a copy of which was attached to the previous amendment as Exhibit E. In response to the rejection of the claims over Cornell, McLaughlin did not dispute that the term “paste” ordinarily implies an abrasive composition. Instead, McLaughlin merely stated that “Cornell adds a silica ‘gelling’ agent and not an abrasive. In fact, Applicant [McLaughlin] respectfully points out that the compositions of Cornell are not practical for use as an *abrasive gel* or scrubbing compound” as opposed to the toothpaste composition of McLaughlin. Amendment, p. 8 (emphasis added). Because McLaughlin himself argued that his toothpaste composition was “practical for use as an abrasive gel or scrubbing compound” (*see id.*), one of ordinary skill in the art would understand the “paste carrier” in Example 4 of McLaughlin to inherently be abrasive.

Accordingly, there is no teaching, suggestion, motivation or other reason that would have prompted one of ordinary skill in the art to modify McLaughlin in order to obtain dental bleaching and desensitizing composition that includes 1) a dental bleaching agent, 2) potassium nitrate, 3) a solvent and 4) thickening agent and which is also substantially free of abrasives.

The claims are also not obvious over claims 1-23 of U.S. Patent No. 6,306,370 (the “’370 patent”). For one thing, none of claims 1-23 of the ‘370 patent are directed to a *method* of bleaching and desensitizing a person’s teeth, nor do any of claims 1-23 of the ‘370 patent teach or suggest a method in which a dental bleaching and desensitizing composition is applied “without scrubbing or brushing”. Accordingly, at the least the method claims of the present Application are unobvious over the *claims* of the ‘370 patent. Moreover, the Examiner fails to cite to any claims of the ‘370 patent that teach or suggest the claimed methods. Accordingly, the Office Action fails to state a *prima facie* obviousness-type double patenting rejection relative to any of method claims 72-85.

Moreover, all of the claims recite dental bleaching and desensitizing compositions that include potassium nitrate within narrowly defined concentration ranges that are neither taught nor suggested by the *claims* of the ‘370 patent. Moreover, the *specification* of the ‘370 patent likewise fails to teach or suggest the claimed concentration *ranges* for the potassium nitrate component. Accordingly, the claims of the present Application claim narrowly tailored species of the much broader genus described in the *claims* of the ‘370 patent.

As stated in the MPEP,

When a single prior art reference which discloses a genus encompassing the claimed species or subgenus but does not expressly disclose the particular claimed species or subgenus, Office personnel should attempt to find additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious.

MPEP 2144.08. See *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (“[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category”). In the present case, the ‘370 patent only discloses a broad genus but not the claimed species (*i.e.*, a broad concentration range of potassium nitrate rather than the narrowly claimed ranges). In addition, the Examiner fails to identify any “additional prior art to show that the differences between the prior art primary reference and the claimed invention as a whole would have been obvious”. For this additional

reason, Applicants submit that the narrowly claimed species of the present invention are patentable over the broad genus described in the claims of the '370 patent.

Moreover, the Office Action fails to properly analyze and compare the differences between claimed species of the present Application and the broad genus of the claims in the '370 patent as required by the Supreme Court in *Graham v. John Deere*. MPEP 2144.08 further states the following in relation to claims which claim a species when the cited art only describes a genus:

In the case of a prior art reference disclosing a genus, Office personnel should make findings as to:

- (A) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus;
- (B) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the usefulness of the genus, and any problems alleged to be addressed by the genus;
- (C) the predictability of the technology; and
- (D) the number of species encompassed by the genus taking into consideration all of the variables possible.

Applying the foregoing test to the present case, one of ordinary skill in the art could not, in light of the claims and specification of the '370 patent, have predicted that a dental bleaching and desensitizing composition having a relatively small quantity of potassium nitrate within the claimed ranges would yield a dental bleaching composition that caused less sensitivity than a dental bleaching and desensitizing composition including a greater quantity of potassium nitrate. Such a result was not "predictable" at the time of the invention (*i.e.*, because potassium nitrate is a desensitizing agent, one of ordinary skill would have predicted at the time of the invention that using more of this component would provide a greater desensitizing effect rather than less). Nevertheless, a comparative study set forth in the Application and cited in previous amendments provided data from which it may be reasonably concluded that dental bleaching and desensitizing compositions that include potassium nitrate within the claimed narrow concentration ranges cause less oral sensitivities than dental bleaching and desensitizing compositions having similar concentrations of dental bleaching agent but even more potassium nitrate. The comparative study demonstrates the patentability of the claimed species because it

shows that the results obtained when using the claimed species relative to oral sensitivities were unpredictable at the time of the invention.

Indeed, the Examiner "is in agreement" that the comparative study shows the surprising and unexpected results of a dental bleaching composition within the claimed species but argues that the claims are not commensurate in scope with the comparative study. This argument fails because it does not properly compare and understand the relevant data. If using an amount of potassium nitrate within the claimed concentration ranges together with a commonly used amount of bleaching agent results in less oral sensitivity caused by the dental bleaching agent than when a larger amount of potassium nitrate outside of the claimed ranges is used, it may be reasonably concluded that this trend would continue when even larger or smaller amounts of the dental bleaching agent are used. Similarly, because using 0.5% potassium nitrate unexpectedly resulted in reduced oral sensitivity compared to when either 3% or 0% is used, it is reasonable to conclude that amounts of potassium nitrate on either side of 0.5% would likely provide greater desensitization compared to either 3% or 0% potassium nitrate.

Moreover, there is no rule or case law that requires Applicants to only claim the specific compositions used in the comparative study, and the Examiner cites to no rule or case law that would require this. On the contrary, MPEP § 716.02(d) states that "the nonobviousness of a broader claimed range can be supported by evidence based on unexpected results from testing a narrower range if one of ordinary skill in the art would be able to determine a trend in the exemplified data which would allow the artisan to reasonably extend the provative value thereof". *In re Kollman*, 595 F.2d 48, 56 201 USPQ 193 (CCPA 1979); *In re Lindner*, 457 F.2d 506, 509, 173 USPQ 356, 359 (CCPA 1972); *In re Clemens*, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980).

For yet these additional reasons, Applicants submit that the claimed invention is unobvious over the claims of the '370 patent and also that the Examiner fails to meet his burden of showing that the claimed species are *prima facie* obvious over the claimed genus of the '370 patent.

In the event the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or which may be overcome by Examiner amendment, the Examiner is requested to contact the undersigned attorney.

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to **Deposit Account**



**No. 23-3178:** (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefore and charge any additional fees that may be required to **Deposit Account No. 23-3178.**

Dated this 19<sup>th</sup> day of May 2010.

Respectfully submitted,



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